REMARKS

Claims 26-38 are pending in this application. Claims 26, 28, 30, and 38 have been amended.

The Applicants respectfully submit that the final rejection is improper because the Examiner did not consider every claim element in her rejection. Second, the Examiner has misinterpreted the cited references.

The Applicants respectfully submit that the final rejection is premature because the Examiner did not address all the elements of the present claims. For example, the Examiner did not mention the claimed element "whereby the presence of HCV ... is confirmed by the color of the detection solution ..." The Applicants respectfully submit that the Examiner should withdraw the final rejection and issue another Office Action that addresses all the elements of the present claims.

Claim 38 has been objected to for informalities. Also, claim 38 has been rejected under 35 USC 112, second paragraph. In light of the foregoing amendment to claim 38, the Applicants respectfully submit that the Indicated informality in claim 38 has been corrected, and that the §112, second paragraph, rejection of claim 38 should be reconsidered and withdrawn.

The claims of this application stand rejected under 35 USC 103(a) as being unpatentable over Resnick in view of Geiger. The Applicants respectfully disagree with

the Examiner and submit that there is no motivation for the cited combination. Even assuming arguendo that Resnick may be properly combined with Geiger, the resulting combination does not provide the features of the present invention as claimed.

Moreover, the claims are self-contained and do not permit the inclusion of features of either of the references not specifically set forth in the claims.

Absent hindsight gained from the present application, there is no motivation to combine the primers of Resnick with a probe from Geiger. The Applicants respectfully submit that the Examiner has misinterpreted Resnick. Resnick does not define a suitable probe as *any* probe hybridizing to a conserved region between the two primers (see page 6 of the first Office Action, paper #6). On the contrary, Resnick actually states at column 14, lines 12-18:

It will be apparent to one of skill in the art that any upstream/downstream primer pair shown in Table 4 is suitable for specifically amplifying the C9 isolate and related isotypes. It will be additionally apparent to select a <u>C9-specific probe</u> suitable for hybridizing the amplified nucleic acid subsequence using as guidance the nucleotide positions provided in Table 4. [emphasis added]

Read as a whole, the Resnick patent provides "materials and methods for assays that are specific to the C9 isolate and distinguish[es] the [C9] isolate from other hepatitis isolates." (column 13, line 35-37). The C9 isolate is disclosed by Resnick as SEQ. ID. NO. 29. Reference to Table 4 reveals that the presently claimed SEQ. ID. NO. 3 is not a C9-specific probe. Also, SEQ. ID. NO. 29 of Resnick does not comprise the presently claimed SEQ. ID. NO. 3. Therefore, one skilled in the art would not be motivated to modify Resnick by substitution for the C9-nonspecific probe disclosed by Geiger.

The Examiner's relationship of Resnick to the present invention is fortuitous. Resnick has no appreciation of how to arrive at Applicants' claimed invention, and nowhere in any of the references of record is there any appreciation of "color" as an important element and feature of the invention.

The Examiner clearly admits that the Resnick disclosure does not teach the specific probe. The Examiner argues that because accidentally, Geiger teaches an HCV probe, that the two references are combinable. The probe in Geiger is merely listed as a part of a catalogue of elements, and there is no teaching or suggestion as to how Resnick can use the Geiger probes. Applicants' respectfully disagree that it would have been obvious without some specific directions. One reading Geiger would not immediately day let us apply this to Resnick without the benefit of Applicants' disclosure. To obtain the probe that Resnick suggests between the two primers requires experimentation, so that there is no clear teaching.

The Examiner's argument that Resnick teaches all of the elements of Applicants' method except for the probe is not well taken because the Examiner has given no consideration of color, which is now included as part of the broad claimed features.

It is difficult to consider what type of comparison test would have to be made between Applicants' claimed subject matter and what the Examiner has selected from the two references because the selections are made in the light and teaching of Applicants' disclosure.

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There is no appreciation of the change of color by any of the references of record.

Even assuming arguendo that Resnick may be properly combined with Geiger, the resulting combination does not provide the features of the present invention as claimed because neither Resnick nor Geiger discloses or even suggests the step of having a detection kit as presently claimed. Specifically, the present application claims a diagnostic kit for the rapid clinical diagnosis of HCV having higher sensitivity and specificity as compared to the conventional assays. Such a kit is not disclosed or even suggested by either Resnick or Geiger when read as a whole, and color is not even considered.

The Applicants respectfully request favorable consideration and that this application be passed to allowance.

Respectfully submitted, LACKENBACH SIEGEL, LLP

Date: June 20, 2003

by:

J Harold Nissen